



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|-------------------------|---------------------|------------------|
| 10/549,409 | 09/14/2005 | Roque Humberto Ferreyro | 101896-0890 | 1699 |
| 21125 | 7590 | 03/11/2009 | | |
| NUTTER MCCLENNEN & FISH LLP | | | EXAMINER | |
| WORLD TRADE CENTER WEST | | | SIGLER, JAY R | |
| 155 SEAPORT BOULEVARD | | | | |
| BOSTON, MA 02210-2604 | | | ART UNIT | PAPER NUMBER |
| | | | 3775 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 03/11/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/549,409 | Applicant(s) FERREYRO ET AL. |
| | Examiner JAY R. SIGLER | Art Unit 3775 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 November 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 7-17,19,20,36-40,50,51,59-62 and 78 is/are pending in the application.

4a) Of the above claim(s) 60 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 7-17,19,20,36-40,50,51,59,61,62 and 78 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsman's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 05 September 2008 and 21 July 2008

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species B in the reply filed on 17 November 2008 is acknowledged.
2. Claim 60 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 November 2008.

Information Disclosure Statement

3. The information disclosure statement filed 21 July 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the some information referred to therein has not been considered.

Specification

4. Claim 19 is objected to because of the following informalities: in line 2, the language "the amount of viscous to be" appears to be missing the words "bone cement", i.e. the language should be "the amount of viscous bone cement to be". Appropriate correction is required.

5. Claim 36 is objected to because of the following informalities: in line 1, the language "The method of claim 37, a separator" appears to be missing the words "bone further comprising", i.e. the language should be "The method of claim 37, further comprising a separator". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8-17, 19, 38, 40, 59, 61, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is new matter: the actuator comprises a hydraulic pump (claim 8); the actuator has a visualization window (claim 9); the visualization window has means for measuring the amount of viscous material being delivered (claim 10, 11, 15, and 16); the delivery tube is noncompliant (claim 12 and 38); the container is adapted to hold at least 3 cc of viscous cement (claim 13; it is noted that this claim language would include containers adapted to hold any amount greater than 3 cc which is not supported originally filed specification); the container comprises a visualization window (claim 14); the container is made from a noncompliant material (claim 17); the amount of fluid in the

vessel is greater than the amount of viscous [bone cement] to be delivered (claim 19); determining the amount of viscous material delivered from a visualization window (claim 40); cooling said bone cement in a manner sufficient to delay its solidification (claim 59); delivering 10 cc of bone cement to a bone (claim 61); and not replacing a cement chamber during a single medical procedure (claim 37).

Therefore, the date of invention of claims 8-17, 19, 38, 40, 59, 61, and 62 is the filing date of said claims, which is 23 December 2005, and will be considered as such for further examination.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 10, 11, 12, 15, 16, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 10 recites the limitation "the visualization window" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

b. Claim 11 recites the limitation "the means for measuring" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

c. Claim 12 recites the limitation "the delivery tube" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

d. Claim 15 recites the limitation "the visualization window" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

e. Claim 16 recites the limitation "the means for measuring" in line 1-2.

There is insufficient antecedent basis for this limitation in the claim.

f. Claim 19 recites the limitation "the vessel" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 8-17, 19, 38, 40, 59, 61, and 62 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 2005/0070915 to Mazzuca et al. (cited by applicant). It is noted that said claims have a date of invention of 23 December 2005.

Mazzuca discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see Abstract), comprising: providing a delivery device (see Fig. 2) having: a container 60 containing a viscous bone cement (see ¶ 50) prior to the bone cement having set, the container having an exit port; an actuator 40 having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic

coupling tube 15 connecting the actuator vessel to the container; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see ¶ 56); and while at least a portion of the patient is subjected to fluoroscopic imaging, actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive a flow of viscous bone cement through the exit port to the desired injection site within the patient (see claim 53). Mazzuca further discloses the additional claim limitations (see claims 1-62)

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 7-9, 12, 13, 20, 36-40, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of US 4,250,887 to Dardik et al. (hereinafter "Dardik").

g. Concerning claims 37 and 78: Gangi discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see *Technique of Injection section*), comprising: providing a delivery device/tube having: a container (i.e. a syringe) containing a viscous bone cement (see page 82, top of the second column) prior to the bone cement having set, the container

having an exit port; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see *Technique of Injection* section); and while at least a portion of the patient is subjected to fluoroscopic imaging, driving a flow of viscous bone cement through the exit port to the desired injection site within the patient (see page 84, column 2, ¶ 1-3).

Gangi does not specifically discloses an actuator having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic coupling tube connecting the actuator vessel to the container; and actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive the flow.

Dardik however suggests a method for delivering a viscous material (col. 3, l. 64) under a radiation field 14 and capable of delivering a viscous material, namely bone cement (naturally follows from similar structure to applicant), to a site in a patient comprising the steps of: providing an actuator 22 having an actuator vessel, the actuator vessel containing an incompressible fluid 35; and a hydraulic coupling tube 33 connecting the actuator vessel to a container 25; and actuating the actuator from a location outside a field of radiation to hydraulically drive the flow of the viscous material from the container (Fig. 1; col. 2, l. 61 to col. 3, l. 15). Dardik suggests this method in order to reduce the radiation exposure to the surgeon (Abstract).

It would have been obvious to someone of ordinary skill in the art at the

time of the invention to add the actuator, hydraulic coupling tube and actuation step of Dardik to the method of Gangi in order to reduce the radiation exposure of the surgeon. The entire modified device of Gangi, in view of Dardik, can be considered a delivery tube in the sense that applicant's entire device can be considered a delivery tube.

h. Concerning claims 7-9, 12, 13, 20, 36 and 38-40: the delivery tube 33 of Dardik is flexible and noncompliant (col. 5, ll. 15-20); a linear actuator 22 (Dardik) is involved; determining the amount delivered can be made from a visualization window 20 (Dardik; col. 5, ll. 3-7); a separator (26 and 38 of Dardik); cannula (see *Technique of Injection* of Gangi).

14. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangi in view of Dardik as applied to claim 37 above and further in view of US 5,431,654 to Nic (hereinafter "Nic").

Gangi, in view of Dardik, fairly suggests the claimed invention but not specifically force amplification. Nic, however, discloses that during injection of bone cement it may be necessary to amplify the force applied as the bone cement becomes less flowable (col. 10, l. 20-34). It would have been obvious to someone of ordinary skill in the art at the time of the invention to amplify the force in the modified invention of Gangi, in view of Dardik, if the bone cement becomes less flowable. Amplifying force using mechanical advantage was a known method at the time of the invention. Therefore, claim 51 would have been obvious because amplifying force using mechanical advantage was a part of the ordinary capabilities of one skill in the art.

Response to Arguments

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733